

REMARKS

Claims 1, 7 and 14-16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over JP 2003-096285 (JP '285) in view of WO 03/0065502 to Kuroki et al (using U.S. 6,984,443 as an English language equivalent).

JP '285 was cited as disclosing mixing D-lactic acid and L-lactic acid resins in a blending ratio of 90:10 to 10:90 overlapping in scope with amended claim 1. The Examiner relied on Kuroki et al as disclosing that poly(L-lactic) and poly(D-lactic) co-saccharide copolymers are functionally equivalent to the corresponding homopolymers. (Col. 4, lines 18-61). The reason for rejection was that it would have been obvious to substitute the poly-D-lactic acid component of the resin composition of JP '285 with a poly(D-lactic-co-saccharide) copolymer because these are said to be recognized in the art as functional equivalents as taught by Kuroki et al.

Further, the Examiner considered that the test data presented in the remarks portion of the Amendment filed May 22, 2007 (showing criticality in an addition amount of resin (2) of from 3 to 25 parts by weight per 100 parts by weight of resin (1) for providing both a higher melting point and crystallization rate such that heat deformation of the resulting molded article is remarkably inhibited) does not establish patentability of the claimed invention. Rather, the Examiner suggested that the claimed addition amount is nothing more than discovery of an optimum or workable range by routine experimentation.

Applicants traverse, and respectfully request the Examiner to reconsider in view of the supplemental test data presented in the Declaration under 37 C.F.R. § 1.132 of Toru YANO submitted herewith (the executed Declaration will be submitted as soon as it is received) and the following remarks.

Kuroki et al only teaches equivalence of poly-D-lactic acid homopolymers and poly(D-lactic-co-saccharide) copolymers in the context of the aliphatic polyester resin composition described therein, which functional equivalence does not necessarily apply to the biodegradable resin composition of the invention.

Regarding this last point, JP '285 concerns a mixture of two specifically defined resins. On the other hand, although Kuroki et al does not preclude addition of other resins, Kuroki et al is mainly directed to an aliphatic polyester resin composition containing a single type of aliphatic polyester resin represented by formula (I). This functional equivalence in Kuroki et al does not necessarily attach to JP '285.

Moreover, Kuroki et al does not differentiate between saccharide copolymers of L-lactic acid and D-lactic acid, whereas the present claims specifically require a mixture of (1) a homopolymer of L-lactic acid and (2) a copolymer of D-lactic acid and a saccharide. Namely, even if Kuroki et al is recognized as establishing functional equivalence of the subject homopolymers and saccharide co-polymers, none of the cited prior art specifically teaches that the resin composition must contain a copolymer of D-lactic acid and a saccharide as an essential component, which characteristic feature is not taught or suggested by the cited prior art.

From a different perspective, criticality of a claimed range as a basis for patentability is described in MPEP §716.02(d) and in §2144.05. Although the Examiner is correct in that generally it is not inventive to discover the optimum or workable ranges by routine experimentation, a particular parameter must first be recognized as a result-effective variable *before the determination of the optimum or workable ranges of the variable might be characterized as routine experimentation.* **Regarding this last point, there is nothing in the prior art which teaches that the addition amount of resin (2) relative to resin (1) is a result-**

effective variable for providing a higher melting point and crystallization rate, or otherwise.

Further, as also discussed in MPEP §2144.05, Applicants may rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range. This is done by showing that the claimed range achieves unexpected results relative to the prior art range.

Applicants have already done this by showing that Sample Nos. 13 and 14 of Example 5 containing resin (2) in an amount of less than 3 parts by weight per 100 parts by weight of resin (1) did not provide the desired increase melting point and crystallization rate.

Applicants supplement the test data presented in Example 5 of the specification in the Rule 132 Declaration of Toru YANO submitted herewith.

Particularly, Table 4' of the Rule 132 Declaration sets forth the data of Sample Nos. 13 to 18 of Table 4 of the specification, and further includes Sample No. 19 containing resin (2) in an amount of 30 parts by weight per 100 parts by weight of resin (1) outside the scope of the present claims. The test data of Table 4' of the Rule 132 Declaration is reproduced below.

Table 4'

No.	13	14	15	16	17	18	19
Resin (1)	100	100	100	100	100	100	100
Resin (2)	-	1	3	5	11	25	30
Melting point (°C)	183	182	188	187	187	200	Unmeasurable
Crystallization rate	Small	Small	Medium	Large	Large	Large	Large
Moldability	good	good	good	good	good	good	poor

As discussed at pages 12-13 of the specification, the biodegradable resin composition of the invention has an improved crystallization rate, i.e., an increased crystallization rate. Thereby,

crystallization is rapidly completed during the molding step of the composition and thus heat deformation of the resulting molding article is remarkably inhibited. As shown in Table 4', Sample Nos. 15 to 18 containing resin (2) in an amount of from 3 to 25 parts by weight per 100 parts by weight of resin (1) provided both a higher melting point and crystallization rate as compared to Sample Nos. 13 and 14 containing resin (2) in an amount of less than 3 parts by weight per 100 parts by weight of resin (1). Sample No. 19 shows that a resin (2) content of 30 parts by weight per 100 parts by weight of resin (1) results in poor moldability. Notably, if the melting temperature is higher than 200°C, the molding temperature becomes close to the decomposition temperature of the polylactic acid, which results in poor moldability. Moreover, Sample Nos. 15 to 18 containing resin (2) relative to resin (1) within the claimed range all provided good moldability. The above-noted results establish criticality in the claimed range of resin (2) relative to resin (1), where resin (1) is restricted to a homopolymer of L-lactic acid and resin (2) is a copolymer of D-lactic acid and a saccharide, which results could not have been expected from the cited prior art.

In view of the above remarks and the test data presented in the Rule 132 Declaration submitted herewith, it is respectfully submitted that the present claims are patentable over JP '285 in view of Kuroki et al, and withdrawal of the foregoing rejection under 35 U.S.C. § 103(a) is respectfully requested.

Claims 1, 7 and 14-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over JP '285 in view of U.S. Patent 5,247,013 to Shinoda. Shinoda was cited as disclosing biocompatible polyester resins which are L- or D-lactic acid-co-saccharides, where use of the saccharide in the copolymer is said to result in improved hydrolyzability (Abstract and col. 4, lines 30-32). The reason for rejection was that it would have been obvious to include the

poly(D-lactic acid) - co-saccharide of Shinoda et al in the resin composition of JP '285 in order to increase the hydrolyzability of the resin. The Examiner further notes that Shinoda et al discloses a saccharide content meeting claims 14-16.

Applicants respond as follows.

Shinoda et al is applied as a secondary reference.

Notably, Shinoda et al gives no preference, one way or the other, to use of a saccharide copolymer of D-lactic or L-lactic acid, whereas the present claims specifically require a mixture of a homopolymer of L-lactic acid and a copolymer of D-lactic acid in a saccharide.

Moreover, the test data presented in the Rule 132 Declaration submitted herewith establishes criticality in an addition amount of resin (2) relative to resin (1) as a basis for patentability. There is nothing in the prior art which teaches that the addition amount of resin (2) relative to resin (1) is a result-effective variable.

Withdrawal of the foregoing rejection under 35 U.S.C. § 103(a) is respectfully requested.

Claim 9 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over JP '285 and Kuroki et al or JP '285 and Shinoda et al further inv view of JP 08073628 (JP '628). JP '628 was cited as disclosing use of a heated mold when molding an article from a poly lactic composition.


Applicants rely on the response above with respect to the rejection over JP '285 and either of Kuroki et al and Shinoda et al.

Withdrawal of all rejections and allowance of claims 1, 7, 9 and 14-16 is earnestly solicited.

In the event that the Examiner believes that it may be helpful to advance the prosecution of this application, the Examiner is invited to contact the undersigned at the local Washington, D.C. telephone number indicated below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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